

## REMARKS

This amendment address the Office Action mailed September 25, 2003. In this Amendment, claim 1 is amended. Claims 1-44 are pending and claims 1-13 were elected in the Response to the Restriction Requirement.

Amended claim 1 specifies that the safety cap cover has a first state where it rotates freely about the pump cap so that rotation of the safety cap cover does not cause rotation of the pump cap. Amended claim 1 also specifies that the safety cap cover has a second state where it contacts the exterior surface of the pump cap so that rotation of the safety cap cover causes rotation of the pump cap to remove the pump cap from the open end of the cartridge chamber. These amendments to claim 1 are supported by the specification at page 33, line 10 through 34, line 15 describing that the safety cap cover may rotate freely around the pump cap in a first state and may be squeezed or pressed down to apply torque to the pump cap in a second state.

The claims were rejected under 35 U.S.C. § 102(e) and 102(b) as being anticipated by U.S. Patent No. 6,585,695 to Adair, U.S. Patent No. 5,634,903 to Kurose, and U.S. Patent No. 6,382,204 to Jansen. Applicants respectfully traverse these rejections.

Claim 1 relates to a medication pump including a cartridge chamber for receiving a medication cartridge. The chamber has a first open end for inserting the medication cartridge. The medication pump also includes a pump cap with a delivery end, a pump end, and an exterior surface. The pump end of the pump cap is described as being configured to rotationally attach to the open end of the cartridge chamber to hold the medication cartridge within the cartridge chamber. The medication pump of claim 1 also includes a safety cap cover that is configured to attach to and enclose the pump cap. The safety cap cover is movable from a first state to a second state on the pump cap. In the first state, the safety cap cover rotates freely around the pump cap and rotation of the safety cap cover does not cause rotation of the pump cap. In the second state, the safety cap cover contacts the exterior surface of the pump cap so that rotation of the safety cap cover causes rotation of the pump cap. None of the three cited references describes a pump as set forth in claims 1-13.

### **Rejection over Adair**

Adair describes a cap 4 that fits over a base 2 on a medication reservoir 1. The reservoir of Adair is capable of being inserted into a pump housing that is not shown in Adair. (Adair, column 3, lines 20-25.) The base 2 includes detents 8 that fit into internal threads 10a on the cap 4. As the cap 4 is turned, the detents 8 slide along cam surfaces 10 until they fit into upper detent openings 7. In this position, the needle 9 of the cap pierces a septum of the base 2. (Adair, column 4, lines 3-14.)

Adair does not show a pump cap rotationally attached to the open end of a cartridge chamber that holds a medication cartridge. Adair is focused on describing the structure of a medication cartridge, not a cartridge chamber for receiving a medication cartridge. The reservoir of Adair is capable of being inserted into a pump housing that is not shown in Adair. (Adair, column 3, lines 20-25.) The base 2, indicated by the Examiner to teach the pump cap of the claims, does not rotationally attach to an open end of a cartridge chamber. Instead, the base 2 attaches to a reservoir 1 and the attachment between the base and the reservoir is not described as rotational. (Adair, Column 3, lines 29-32.) During an Examiner Interview on December 15, 2003, the Examiner explained that he was interpreting the reservoir 1 to be a cartridge chamber that could hold within it a medication cartridge. However, Applicants respectfully note that Adair does not teach that the reservoir 1 is capable of receiving another medication cartridge. Also, the base 2 of Adair does not rotationally attach to anything.

Further, Adair does not teach a safety cap cover that has a second state where the rotation of the safety cap cover can cause rotation of the pump cap to remove the pump cap from the open end of a cartridge chamber. The base 2 does not rotationally attach to the reservoir 1 and the rotation of the cap 4 in Adair is not to facilitate removal of the base 2 from the reservoir 1. Instead, the cap 4 rotates to move a needle 7 from a separated position to a piercing position.

In addition, Adair does not describe a safety cap cover that can rotate freely around a pump cap in a first state, or a safety cap cover that does not cause rotation of the pump cap in the first state, as specified in the amended claim 1. In the Examiner Interview, the Examiner explained his view that any rotation was a free rotation. Claim 1 has now been amended to specify that the safety cap cover does not cause rotation of the

pump cap in the first state. In Adair, the cap 4 cannot rotate further once the detents 8 are positioned within the upper detent openings 7 unless the base 2 also rotates.

For at least these reasons, claim 1 is patentable over Adair. For at least these same reasons, dependent claims 2-13 are also patentable over Adair.

In addition, claim 3 specifies how deforming moves the safety cap cover. In addition to the fact that the cap 4 of Adair does not move between the specified first and second states, the cap 4 of Adair also is not described as deforming. In the Examiner Interview, the Examiner explained his position that the frictional interaction between the detents 8 on the base 2 and the cam surfaces 10 on the cap 4 caused some deformation of the cap 4 of Adair. Applicants respectfully disagree and request a further explanation of how the cap 4 deforms to move between a first and second position. As a result, claim 3 is further patentable over Adair

#### **Rejection over Kurose**

Kurose does not show a pump cap rotationally attached to the open end of a cartridge chamber that holds a medication cartridge. Kurose describes a syringe with a syringe body 5 and does not describe any cartridge chamber for receiving a medication cartridge. During the Examiner Interview, the Examiner explained that he was interpreting the syringe body 5 to be a cartridge chamber that could hold within it a medication cartridge. However, Applicants respectfully note that Kurose does not teach that the syringe body 5 is capable of receiving a medication cartridge and instead describes that the syringe body 5 will receive a liquid such as liquid medication: "The plunger 4 is slidably housed in the syringe body 5 so as to be moved in the axial direction thereof in a liquid-tight manner. At the time of use, the plunger 4 is moved in the axial direction thereof so as to withdraw or inject a liquid medication." (Kurose, Column 5, lines 6-12.)

Further, Kurose does not show a safety cap cover that has a second state where the rotation of the safety cap cover can cause rotation of the pump cap to remove the pump cap from the open end of a cartridge chamber. The Office Action asserts that the needle 2 of Kurose teaches a safety cap cover and the needle-mounting member 3 of Kurose teaches a pump cap. Rotation of the needle 2 attaches it to or detaches it from the needle-mounting member 3. (Kurose, Column 6, lines 27-42.) Kurose does not show a safety cap cover that has a second state where the rotation of the safety cap cover can

cause rotation of the pump cap to remove the pump cap from the open end of a cartridge chamber.

In addition, Kurose does not describe a safety cap cover that has a first state where the safety cap cover can rotate freely around a pump cap and rotation of the safety cap cover does not cause rotation of the pump cap. The needle 2 of Kurose can be rotated onto or off of the needle mounting member 3, but Kurose does not describe that the needle 2 may rotate further without causing the rotation of the needle mounting member 3.

For at least these reasons and others, claim 1 is patentable over Kurose. In addition, many of the features of the dependent claims 2-13 are also not taught by Kurose.

#### **Rejection over Jansen**

Jansen shows a drug delivery system such as for applying a nasal drug including a syringe that is retained within a holder 24. The holder 24 includes a distal portion 26 and a proximal portion 28. The Office Action states the argument that the distal portion of the holder 26 teaches a pump cap and a rim 38 shown in Figure 11 teaches a safety cap cover. Applicants respectfully point out that Jansen does not disclose many of the features of claim 1 and the dependent claims. For example, Jansen does not show a pump cap configured to rotationally attach to the open end of a cartridge chamber. During the Examiner Interview, the Examiner explained that he was interpreting the syringe 22 of Jansen to be a cartridge chamber that could hold within it a medication cartridge. However, Applicants respectfully note that Jansen does not teach that the syringe 22 is capable of receiving another medication cartridge. Instead, the "syringe is preferably pre-filled with the substance such as a drug, vaccine or the like to be delivered prior to inserting the syringe into the holder 24. A stopper 40 is slidably positioned in fluid-tight engagement inside the barrel 30. A sealing or tip cap 42 may be fitted over the tip 36 to prevent the loss of fluid through the orifice prior to use of the assembly." (Jansen, Column 6, Lines 23-31.)

In addition, Jansen does not show a safety cap cover that encloses a pump cap. In fact, the rim 38 asserted to be the safety cap is a part of a structure that is enclosed by the distal portion of the holder 26, which is asserted to be a pump cap, as shown in Figure 11.

Further, Jansen does not teach a safety cap cover movable between a first state and a second state where in the second state the safety cap cover rotates to cause rotation of the pump cap to remove the pump cap from an open end of a cartridge chamber.

For these reasons and others, claims 1-13 are patentable over Jansen.

### Interview Summary

On December 15, 2003, Applicants undersigned representative met with Examiner DeSanto to discuss the references. The lack of a safety cap cover that rotates freely in Adair was discussed along with the definition of "rotates freely." The teachings of Jansen and Kurose were also discussed. Agreement on the claims was not reached.

### Conclusion


In light of the amendments and arguments herein, Applicants respectfully request allowance of the pending claims at an early date. The Examiner is encouraged to contact Applicants undersigned representative with any questions or issues that would prevent allowance of the case.

Respectfully submitted,



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